PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
20040158		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/ES2004/000169	16.04.2004	16.04.2003
International Patent Classification (IPC) or both national classification and IPC		
A61L2/18		
Applicant		
NEOCHEMICAL DESARROLLOS AVANZADOS, S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.12.2004	02.09.2005
Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Ladenburger, C Telephone No. +49 89 2399-8276

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/ES2004/000169

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-25 filed with the demand

Claims, Numbers

1-24 received on 18.07.2005 with letter of 15.07.2005

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: English , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☒ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-24
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

see separate sheet

V.2 Reasoned statement; Citations and explanations

1. Reference is made to the following documents cited in the search report:
D1= EP-A-0 775 439
D2= JP-A-6 321 711 (+ PAJ/JPO and WPI/DERWENT abstracts)
D3= JP-A-5 305 126 (+ PAJ/JPO and WPI/DERWENT abstracts)

2. The prior art documents D1-D3 (see e.g. D1, claim 1, col.1 l.7-10, Examples 7, 11-14; D2, PAJ abstract; D3, WPI abstract) already disclose the use of compositions comprising ≤ 20% of a (C1-C20) dialkyl ketone peroxide, e.g. methyl ethyl ketone peroxide (MEKP), as germicides and fungicides in sterilizing and disinfecting methods.
The subject-matter of the present application therefore is not new (Articles 33(1), 33(2) PCT).

Concerning the reply of 15.07.2005 to the written opinion dated 17.03.2005, applicant's attention is drawn to e.g. claims 3,8,14 of D1 (15-20%, 12-18%, 14%), and to the fact that current claim 1 does not exclude the presence of another active ingredient (see "a composition that **comprises** ...").

3. The application also calls for several remarks as concerns clarity (Article 6 PCT).

3.1 It is general knowledge that e.g. MEKP is a hazardous product, reacts violently with various organic and metallic materials, is explosive and a severe irritant for skin and mucous membranes. Thus, it is questionable whether MEKP can be used safely at dosages as high as 20%, especially if applied to the human or animal body (see e.g. 3 first lines of claim 18).
MEKP does not appear to be a non-toxic, non-ecotoxic product (see description p.1 l.7, p.4 l.21).
In the light of the passage p.6 l.32-33, that a sterilizing agent eliminates "all life forms", it is questionable how such agent can be used in human or animal therapy (see claim 18, first line).

3.2 The term "isomer" used e.g. in claim 1 is unclear in the context of the invention. It is

evident that not any structural isomers of the dialkyl ketone peroxides (e.g. the polyol $HO-CH_2-CH(OH)-CH(OH)-CH_2-OH$ is also an isomer of MEKP) will exhibit biocidal properties.
The polymeric forms of a compound (see description p.8 l.12-26) are usually not covered by the term "isomer".

3.3 On p.8 l.2-5, it is stated that the alkyl groups can be unsaturated, substituted by diverse organic or inorganic groups. This statement renders the subject-matter of e.g. claim 1 unclear, since unsaturated or substituted groups are normally not covered by the sole term "alkyl".

3.4 The compositions used in claims 1 and 19 comprise a dialkyl ketone peroxide at a percentage by volume **less than** or equal to 20%. It is noted that such definition also includes very low percentages, close to zero, e.g. 0.1 ppm. It is doubtful that the composition is effective at such dosage of active compound.

3.5 Preferred embodiments (see in particular independent claims 1 and 19) should be claimed in separate, dependent claims.

3.6 The description must be brought into accord with the amended claims.

CLAIMS

1. Use of a composition that comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 20%, as a biocide, sterilizing, antiseptic, disinfecting or anti-parasitic agent.

2. The use according to claim 1, characterised in that the composition comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, in a percentage by volume less than or equal to 5%, preferably less than or equal to 0.3%.

3. The use according to anyone of previous claims, characterised in that said composition comprises methyl ethyl ketone peroxide, or an isomer or a mixture of isomers of the same.

4. The use according to anyone of previous claims, characterised in that said composition comprises water, or an adequate organic solvent or an oil as an excipient.

5. The use according to claim 4, characterised in that the organic solvent is an alcohol.

6. The use according to claim 5, characterised in that the alcohol is selected from: hexylene glycol, polyethylene glycol 200, propylene glycol and glycerin-formal, diacetone alcohol, ethanol, n-propanol or isopropanol

7. The use according to anyone of claims 1-6, as a bactericide.

8. The use according to anyone of claims 1-6, as a virucide.

9. The use according to anyone of claims 1-6, as a fungicide.

10. The use according to anyone of claims 1-6, as a sporicide.

11. The use according to anyone of claims 1-6, as a mycobactericide.

12. The use according to anyone of claims 1-6, as a protocide.

13. The use according to anyone of claims 1-6, as an algicide.

14. The use according to anyone of claims 1-6, as a prionicide.

15. The use according to anyone of claims 1-6, as an insecticide.

16. The use according to anyone of claims 1-6, as an arachnicide.

17. The use according to anyone of claims 1-6, as a miticide.

18. The use according to the previous claims, applied to human and animal therapy, human and animal hygiene, the washing and disinfection of healthy or damaged skin both in man and animals, packing, wrapping, medical and industrial instruments, sanitary surfaces and healthcare environments, premises, surfaces in general, industrial installations, refrigeration towers, air conditioning conduits, machinery and installations in the food industry, agriculture and fisheries installations, sanitary hot water circuits, purification of drinking water for human or animal consumption, or any other application: industrial, domestic, environmental, agricultural, forestry, urban, pharmaceutical, civil, military, police purposes, scientific, technological, spatial, geological, healthcare or health prevention.

19. Method of sterilisation, disinfection, asepsia or deparasitisation that comprises the application of a composition comprising a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 20%.

20. The method according to claim 19, characterised in that said composition comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 5%, preferably less than or equal to 0.3%.

21. The method according to claims 19-20, characterised in that said composition comprises methyl ethyl ketone peroxide, or an isomer or a mixture of isomers of the same.

22. The method according to claims 19-21, characterised in that said composition comprises water, an adequate organic solvent or an oil as an excipient.

23. The method according to claim 22, characterised in that the organic solvent is an alcohol.

24. The method according to claim 23, characterised in that the alcohol is selected from hexylene glycol, polyethylene glycol 200, propylene glycol and glycerin-formal, diacetone alcohol, ethanol, n-propanol or isopropanol.